Exhibit - 1

CT Corporation

Service of Process Transmittal

09/20/2021
CT Log Number 540273595

TO: Megan Sousa
Johnson & Johnson
1 JOHNSON AND JOHNSON PLZ
NEW BRUNSWICK, NJ 08933-0002

RE: **Process Served in Indiana**

FOR: DePuy Orthopaedics, Inc. (Domestic State: IN)

ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:

TITLE OF ACTION:	Re: Patricia Layton // To: DePuy Orthopaedics, Inc.
DOCUMENT(S) SERVED:	Summons, Addresses, Verified Complaint, Verification, Attachment(s)
COURT/AGENCY:	Suffolk County Supreme Court, NY Case # 6176202021
NATURE OF ACTION:	Product Liability Litigation - Personal Injury - Depuy ASR Hip Implant Device
ON WHOM PROCESS WAS SERVED:	C T Corporation System, Indianapolis, IN
DATE AND HOUR OF SERVICE:	By Process Server on 09/20/2021 at 15:06
JURISDICTION SERVED :	Indiana
APPEARANCE OR ANSWER DUE:	Within 20 days after service, exclusive of the day of service
ATTORNEY(S) / SENDER(S):	Nicholas R. Farnolo Napoli Shkolnik, PLLC 400 Broadhollow Road Suite 305 Melville, NY 11747 212-397-1000
ACTION ITEMS:	CT has retained the current log, Retain Date: 09/20/2021, Expected Purge Date: 10/05/2021 Image SOP Email Notification, Ra-Jjcus Ldsop RA-JJCUS-LDSOP@its.jnj.com Email Notification, Janet Lucas Jlucas14@its.jnj.com
REGISTERED AGENT ADDRESS:	C T Corporation System 334 North Senate Avenue Indianapolis, IN 46204 855-844-0739 ServiceSolutionsTeam@wolterskluwer.com

The information contained in this Transmittal is provided by CT for quick reference only. It does not constitute a legal opinion, and should not otherwise be relied on, as to the nature of action, the amount of damages, the answer date, or any other information contained in the included documents. The recipient(s) of this form is responsible for reviewing and interpreting the included documents and taking appropriate action, including consulting with its legal and other

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TO: Megan Sousa
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NEW BRUNSWICK, NJ 08933-0002

RE: **Process Served in Indiana**

FOR: DePuy Orthopaedics, Inc. (Domestic State: IN)

advisors as necessary. CT disclaims all liability for the information contained in this form, including for any omissions or inaccuracies that may be contained therein.

CT

Service intended for:

Depuy Orthopaedics, Inc.

CT Corporation

Service of Process Transmittal

09/20/2021
CT Log Number 540273669

TO: Megan Sousa
Johnson & Johnson
1 JOHNSON AND JOHNSON PLZ
NEW BRUNSWICK, NJ 08933-0002

RE: **Process Served in Indiana**

FOR: DePuy Synthes, Inc. (Domestic State: DE)

ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:

TITLE OF ACTION:	Re: Patricia Layton // To: DePuy Synthes, Inc.
DOCUMENT(S) SERVED:	Summons, Addresses, Verified Complaint, Attachment(s)
COURT/AGENCY:	Suffolk County Supreme Court, NY Case # 6176202021
NATURE OF ACTION:	Product Liability Litigation - Personal Injury - Depuy ASR Hip Implant
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TO: Megan Sousa
Johnson & Johnson
1 JOHNSON AND JOHNSON PLZ
NEW BRUNSWICK, NJ 08933-0002

RE: **Process Served in Indiana**

FOR: DePuy Synthes, Inc. (Domestic State: DE)

advisors as necessary. CT disclaims all liability for the information contained in this form, including for any omissions or inaccuracies that may be contained therein.

CT

Service intended for:

Depuy Synthes, Inc.

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK

----------X

PATRICIA LAYTON,

Plaintiff,

-against-

DEPUY SYNTHES SALES, INC. d/b/a DEPUY SYNTHES JOINT RECONSTRUCTION; MEDICAL DEVICE BUSINESS SERVICES, INC.; DEPUY ORTHOPAEDICS, INC.; DEPUY SYNTHES PRODUCTS, INC.; DEPUY SYNTHES, INC.; DEPUY MITEK, LLC; DEPUY, INC.; DEPUY INTERNATIONAL, LTD.; DEPUY IRELAND UNLIMITED COMPANY; DEPUY SYNTHES JOHNSON & JOHNSON IRELAND, LTD.; JOHNSON & JOHNSON INTERNATIONAL; JOHNSON & JOHNSON; and JOHNSON & JOHNSON SERVICES, INC.,

Defendants.

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Index No:

SUMMONS

To the above-named defendants:

YOU ARE HEREBY SUMMONED to answer the complaint in this action and to serve a copy of your answer, or, if the complaint is not served with this summons, to serve a notice of appearance, on the plaintiff's attorney within 20 days after the service of this Summons, exclusive of the day of service (or within 30 days after the service is complete if this summons is not personally delivered to you within the State of New York); and in case of you fail to appear or answer, judgment will be taken against you by default for the relief demanded in the complaint.

The basis of venue designated above is that it is the Plaintiff's county of residence is SUFFOLK COUNTY.

JURY TRIAL DEMANDED

Dated: New York, New York
September 14, 2021

Yours, etc,
NAPOLI SHKOLNIK PLLC

Nicholas R. Farnolo, Esq.
400 Broadhollow Road, Suite 305
Melville, NY 11747
T: (212) 397-1000
F: (646) 843-7619
Attorneys for Plaintiff

Defendants' addresses:

DePuy Synthes Sales, Inc. d/b/a DePuy Synthes Joint Reconstruction
325 Paramount Drive
Raynham, Massachusetts 02767

Medical Device Business Services, Inc.
700 Orthopaedic Drive,
Warsaw, Indiana 46582

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive,
Warsaw, Indiana 46582

DePuy Synthes Products, Inc.
325 Paramount Drive,
Raynham, Massachusetts 02767

DePuy Synthes, Inc.
700 Orthopaedic Drive,
Warsaw, Indiana 46581

Depuy Mitek, LLC
325 Paramount Drive,
Raynham, Massachusetts 02767

DePuy, Inc.
Corporation Trust Center, 1209 Orange Street,
Wilmington, Delaware 19801

Depuy International, Ltd.
St. Anthony's Road, Beeston, Leeds,
West Yorkshire, LS11 8DT, United Kingdom

DePuy Ireland Unlimited Company
Loughbeg Industrial Estate,
Loughbeg Ringaskiddy, County Cork, Ireland

DePuy Synthes Johnson & Johnson Ireland, Ltd.
Unit 2, Block 10, Blanchardstown Corporate Park,
Dublin 15, Ireland

Johnson & Johnson International
One Johnson & Johnson Plaza,
New Brunswick, New Jersey 08933

Johnson & Johnson
One Johnson & Johnson Plaza,
New Brunswick, New Jersey 08933

Johnson & Johnson Services, Inc.
One Johnson & Johnson Plaza,
New Brunswick, New Jersey 08933

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK

----------X

PATRICIA LAYTON,

Plaintiff,

-against-

DEPUY SYNTHES SALES, INC. d/b/a DEPUY SYNTHES JOINT RECONSTRUCTION; MEDICAL DEVICE BUSINESS SERVICES, INC.; DEPUY ORTHOPAEDICS, INC.; DEPUY SYNTHES PRODUCTS, INC.; DEPUY SYNTHES, INC.; DEPUY MITEK, LLC; DEPUY, INC.; DEPUY INTERNATIONAL, LTD.; DEPUY IRELAND UNLIMITED COMPANY; DEPUY SYNTHES JOHNSON & JOHNSON IRELAND, LTD.; JOHNSON & JOHNSON INTERNATIONAL; JOHNSON & JOHNSON; and JOHNSON & JOHNSON SERVICES, INC.,

Defendants.

----------X

Index No:

VERIFIED COMPLAINT

COMES NOW Plaintiff PATRICIA LAYTON, who by and through the undersigned counsel, hereby submits this complaint against the above-named defendants, her relief deemed just and proper arising from the injuries of Plaintiff, as follows:

PARTIES

1. At all times relevant hereto, Plaintiff PATRICIA LAYTON was a resident of the State of New York.

2. Defendant DePuy Synthes Sales, Inc. d/b/a/ DePuy Synthes Joint Reconstruction ("DSS") is and, at all times relevant, was a corporation organized and existing under the laws of the State of Massachusetts, with its principal place of business located at 325 Paramount Drive, Raynham, Massachusetts 02767, and regularly conducted business in the State of New York by selling and distributing its products in New York. Upon information and belief, DSS is a division

and/or subsidiary of DePuy Orthopaedics, Inc. ("DOI"). DSS is a wholly-owned subsidiary of Johnson & Johnson, a publicly traded company.

3. DSS designs, makes, imports, distributes, sells and/or offers for sale total hip replacement prostheses, including the DEPUY ASR HIP IMPLANT Device. DSS was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the DEPUY ASR HIP IMPLANT Device, as well as monitoring and reporting adverse events related to the DEPUY ASR HIP IMPLANT Device.

4. Defendant Medical Device Business Services, Inc. ("Device Business Services") is and, at all times relevant, was a corporation organized and existing under the laws of the State of Indiana, with its headquarters and principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46582, and regularly conducted business in the State of New York by selling and distributing its products in New York. Device Business Services is a wholly-owned subsidiary of Johnson & Johnson, a publicly traded company.

5. Defendant DePuy Orthopaedics, Inc. ("DOI") is and, at all times relevant, was a corporation organized and existing under the laws of the State of Indiana, with its headquarters and principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46582, and regularly conducted business in the State of New York by selling and distributing its products in New York. DOI is a wholly owned subsidiary of Johnson & Johnson, a publicly traded company.

6. At all times relevant, DOI and Device Business Services were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, packaging, labeling and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the DEPUY ASR HIP

IMPLANT Device, as well as monitoring and reporting adverse events associated with DEPUY ASR HIP IMPLANT. DOI and Device Business Services participated in the decision-making process and response of the Defendants, if any, related to DEPUY ASR HIP IMPLANT adverse events and/or MAUDE reports.

7. Defendant DePuy Synthes Products, Inc. ("DSP") is and, at all times relevant, was a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 325 Paramount Drive, Raynham, Massachusetts 02767, and regularly conducted business in the State of New York by selling and distributing its products in New York.

8. DSP is division of DOI. DSP is a wholly-owned subsidiary of Johnson & Johnson, a publicly traded company.

9. Defendant DePuy Synthes, Inc. ("DS") is and, at all times relevant, was a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46581, and at all relevant times was doing business in the State of New York by selling and distributing its products in New York.

10. Defendant DePuy Mitek, LLC ("DM") is and, at all times relevant, was a limited liability company organized and existing under the laws of the State of Massachusetts, with its principal place of business located at 325 Paramount Drive, Raynham, Massachusetts 02767, and regularly conducted business in the State of New York by selling and distributing its products in New York. DM operates as a subsidiary of DS, which is a wholly owned subsidiary of Johnson & Johnson, a publicly traded company.

11. DSP, DS, and DM design, manufacture, test, package, label, distribute, sell and/or offer for sale certain total hip replacement prostheses, including the DEPUY ASR HIP IMPLANT Device.

12. Defendant DePuy, Inc. is and, at all times relevant, was a corporation organized and existing under the laws of the State of Delaware, with its headquarters and principal place of business at Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801. At all relevant times, DePuy, Inc. conducted regular and sustained business in New York by selling and distributing its products in New York.

13. As DOI's parent company, DePuy, Inc. is and, at all relevant times, was involved in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the DEPUY ASR HIP IMPLANT Device, as well as monitoring and reporting adverse events associated with DEPUY ASR HIP IMPLANT. Upon information and belief, DePuy, Inc. participated in reviewing, investigating and/or responding to FDA adverse events and/or MAUDE reports related to the DEPUY ASR HIP IMPLANT Device, and in the decision of whether to submit reports of DEPUY ASR HIP IMPLANT failures to the FDA.

14. Defendant DePuy International, Ltd. ("DIL") is a public entity or corporation organized and existing under the laws of the United Kingdom, with its principal place of business at St. Anthony's Road, Beeston, Leeds, West Yorkshire, LS11 8DT, United Kingdom, and at all times relevant was doing business within the United States. At all relevant times, DePuy, International, Ltd. conducted regular and sustained business in New York by selling and distributing its products in New York.

15. DIL makes, designs, imports, distributes, labels, sells and/or offers for sale certain total hip replacement prostheses, including the DEPUY ASR HIP IMPLANT Device.

16. DePuy Ireland Unlimited Company ("DePuy Ireland") is a company and a citizen of Ireland with its principal place of business located at Loughbeg Industrial Estate, Loughbeg

Ringaskiddy, County Cork, Ireland, and at all relevant times was doing business within the United States. At all relevant times, DePuy Ireland Unlimited Company conducted regular and sustained business in New York by selling and distributing its products in New York.

17. At all times relevant, DePuy Ireland was involved in the business of designing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly, through third parties or related entities, numerous orthopedic products, including the DEPUY ASR HIP IMPLANT Device, as well as monitoring and reporting adverse events associated with DEPUY ASR HIP IMPLANT. DePuy Ireland had a role in the decision-making process and response of the Defendants, if any, related to the handling of adverse events and MAUDE reports concerning DEPUY ASR HIP IMPLANT Device failures.

18. DePuy Synthes Johnson & Johnson Ireland, Ltd. ("Synthes Ireland") is an entity doing business and organized in Ireland with its principal place of business located at Unit 2, Block 10, Blanchardstown Corporate Park, Dublin 15, Ireland, and at all relevant times was doing business within the United States. At all relevant times, DePuy Synthes Johnson & Johnson Ireland Ltd. conducted regular and sustained business in New York by selling and distributing its products in New York.

19. At all times relevant, Synthes Ireland was involved in the business of designing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly, through third parties or related entities, numerous orthopedic products, including the DEPUY ASR HIP IMPLANT Device, as well as monitoring and reporting adverse events associated with DEPUY ASR HIP IMPLANT.

20. Synthes Ireland had a role in the decision-making process and response of the Defendants, if any, related to the handling of adverse events and/or MAUDE reports concerning DEPUY ASR HIP IMPLANT Device failures. Defendants DSS, DOI, DIL, DSP, DS, DM, DePuy,

Inc., Device Business Services, DePuy Ireland and Synthes Ireland are collectively referred to as "DePuy" and the "DePuy Synthes Companies." The DePuy Synthes Companies are part of the Johnson & Johnson Family of Companies. The DePuy Synthes Companies are a group of functionally-integrated companies with shared management, administrative and general functions, including human resources, legal, quality control, customer service, sales administration, logistics, information technology, compliance, regulatory, finance and accounting and are considered a single business enterprise.

21. Defendant Johnson & Johnson International is and, at all times relevant, was a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, and regularly conducted business in the State of New York by selling and distributing its products in New York.

22. Defendant Johnson & Johnson is the parent company of Defendants DePuy International Limited, DePuy Ireland Unlimited Company and DePuy Synthes Johnson & Johnson Ireland Ltd.

23. Defendant Johnson & Johnson is the alter ego of wholly owned subsidiaries Defendants, DePuy International Limited; DePuy Ireland Unlimited Company and DePuy Synthes Johnson & Johnson Ireland Ltd ("subsidiary Defendants"). Defendant Johnson & Johnson has used these named subsidiary Defendants as its agents; and/or Defendant Johnson & Johnson and the named subsidiary Defendants are one single integrated enterprise.

24. As one of DePuy's parent companies, Johnson & Johnson International is and, at all relevant times, was involved in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the

DEPUY ASR HIP IMPLANT Device, as well as monitoring and reporting adverse events associated with DEPUY ASR HIP IMPLANT. Johnson & Johnson International participated in the decision-making process and response, if any, related to adverse events and/or MAUDE reports concerning the DEPUY ASR HIP IMPLANT Device.

25. Plaintiff has suffered personal injuries as a direct and proximate result of DePuy Synthes Sales, Inc. d/b/a/ DePuy Synthes Joint Reconstruction; Medical Device Business Services, Inc.; DePuy Orthopaedics, Inc.; DePuy Synthes Products, Inc.; DePuy Synthes, Inc.; DePuy Mitek, LLC.; DePuy, Inc.; DePuy International, Ltd.; DePuy Ireland Unlimited Company; DePuy Synthes Johnson & Johnson Ireland Ltd.; Johnson & Johnson International; Johnson & Johnson; and Johnson & Johnson Services Inc. (collectively "Defendants") conduct and misconduct, as described herein, in connection with the design, development, manufacturing, testing, packaging, advertising, marketing, distributing, labeling, warning and sale of the DePuy ASR Hip Implant Device.

JURISDICTION AND VENUE

26. The amount in controversy alleged by Plaintiff will exceed seventy-five thousand dollars ($75,000.00).

COMMON ALLEGATIONS APPLICABLE TO ALL COUNTS

PLAINTIFF SPECIFIC BACKGROUND

27. On March 20, 2008, the Plaintiff underwent a total hip arthroplasty to her right hip.

28. The surgeon, Jonathan Mallen, M.D., inserted a "DePuy Summit hip stem size #3 with a metal-on-metal articulation and a 52mm ASR" cup.

29. This surgery was medically indicated because the Plaintiff suffered from right hip osteoarthritis.

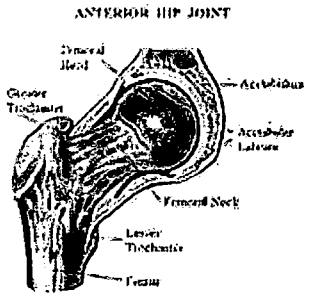
30. Subsequently, the Plainitff's labwork came positive for elevated levels of cobalt and chromium.

31. On February 10, 2020, the Plaintiff went for a revision and explant surgery of the DEPUY ASR HIP IMPLANT product with Keith R Reinhardt, M.D.

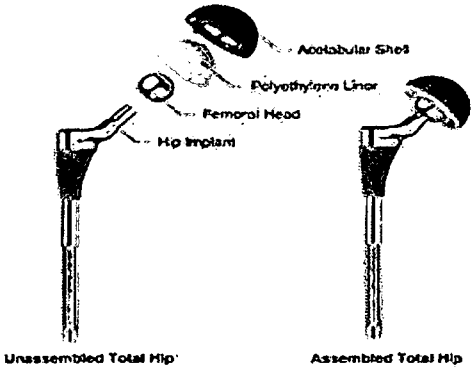
FACTUAL BACKGROUND

A. DePuy's ASR Hip implant has not been adequately tested or approved by the FDA

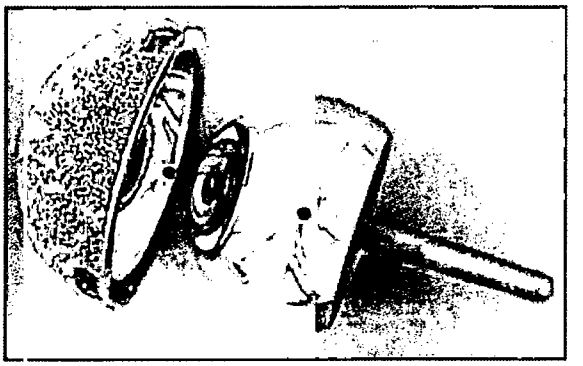
32. The hip joint is where the femur connects to the pelvis. The joint is made up of the femoral head (a ball-like structure at the very top of the femur) rotating within the acetabulum (a cup-like structure at the bottom of the pelvis.) In a healthy hip, both the femur and the acetabulum are strong and the rotation of the bones against each other is cushioned and lubricated by cartilage and fluids. Over time, age and wear break down the cartilage. This forces the bone of the femur to rub directly against the bone of the acetabulum, and it causes severe pain and immobility.



33. A total hip replacement replaces the body's natural joint with an artificial one, usually made out of metal and plastic. A typical total hip replacement system consists of four separate components: (1) a femoral stem (labeled as "hip implant" in the diagram to the left), (2) a femoral head, and (3) a liner, and (4) an acetabular shell. After the surgeon hollows out a patient's femur bone, the femoral stem is implanted. The femoral head is a metal ball that is fixed on top of the femoral stem. The femoral head forms the hip joint when it is placed inside the polyethylene liner and acetabular shell.



34. The DePuy ASR hip implant that is at issue in this lawsuit has a different design, one that puts the metal femoral ball directly in contact with a metal acetabular cup. The design of the DePuy ASR hip is unorthodox, it was not sufficiently tested by the Defendants, and it has never been approved by the FDA as being safe or effective.



35. The acronym "ASR" stands for "Articular Surface Replacement." ASR is a surgical procedure that is an alternative to a total hip replacement procedure. In an ASR procedure, only the articular surface of the hip (the acetabular cup and the femoral ball) are replaced. On the other hand, a total hip replacement includes not only the acetabular cup and femoral ball, but also a large piece of metal (known as a femoral stem) that is implanted deep into the patient's femur and on which the femoral ball is affixed.

36. If DePuy wanted to market its ASR Hip for use in an ASR surgery, the FDA would have required DePuy to conduct clinical trials and prove that the product is both safe and effective. and effective. DePuy would then need to submit an application asking the FDA to approve the device, and it would be required to monitor the long-term safety and performance of the product once it was placed on the market. DePuy wanted to market its ASR Hip System in the United States, but it didn't want to go through the trouble or incur the expense of clinical trials or obtaining FDA approval.

37. Instead of assuring the safety of the ASR through clinical trials, DePuy relied on a loophole in FDA regulations that allows DePuy to market its ASR Hip without conducting any

clinical trials and without ever obtaining FDA approval. DePuy told the FDA that the components of the ASR Hip System would be used for total hip replacements, not for ASR surgeries. DePuy then told the FDA that its design was "substantially equivalent" to other hip products on the market. By doing so, DePuy was able to skirt the FDA regulations that would have required clinical trials and FDA approval, and it was able to put the ASR Hip System on the market in the United States ostensibly for use in an application for which it was not designed, a total hip replacement. To this day, despite being implanted in the bodies of thousands of Americans who believed that the devices are safe, DePuy's ASR Hip System has never been approved by the FDA as being safe or effective.

38. While most hip replacements use a polyethylene plastic acetabular cup, DePuy's ASR Hip System has a critical difference: it uses a metal acetabular cup. By using a metal acetabular cup and a metal femoral ball, the ASR Hip forces metal to rub against metal with the full weight and pressure of the human body. Because of Defendants' defective design for the ASR Hip, hundreds of patients—including Ms. Patricia Layton—have been forced to undergo surgeries to replace the failed hip implants.

B. After hundreds of failures, DePuy and the FDA finally recalled the ASR Hip

39. It wasn't long after DePuy launched the ASR hip in 2005 that reports of failures began flooding into DePuy. For example, just a few months after it began selling the ASR Hip System, in May 2006, DePuy received a complaint from a doctor who reported that the ASR acetabular cup had failed in a patient who had to undergo a revision surgery to replace the defective cup. DePuy closed its investigation of this complaint, finding that "corrective action is not indicated."

40. DePuy would go on to receive hundreds of similar complaints reporting that the ASR Hip System had failed due to premature loosening of the acetabular cup and that the failure had forced patients to undergo painful and risky surgeries to remove and replace the failed hip

component. As the New York Times chart to the right shows, by 2007 over 100 reports had been sent to DePuy. By the end of 2008, that had skyrocketed to well over 300 reports.

41. By the time DePuy sold the ASR Hip System to Patricia Layton in March 2008, DePuy had received several complaints that the ASR hip had failed. Consequently, DePuy was fully aware that the ASR Hip System was defective and that patients already had been injured by that defect. This is confirmed by Dr. Stephen Graves, the Director of the Australian Orthopaedic Association's National Joint Replacement Registry. Dr. Graves believes that the data available to DePuy had shown for some time that the ASR had been failing early at a significantly higher rate than its competitors' devices.

42. The defect in the ASR hip appears to be design-related. Several orthopedic specialists have opined that the design of the ASR acetabular cup, which is shallower than acetabular cups made by other companies, is at the heart of the hip implant's problems. For example, Dr. Harlan C. Amstutz, an orthopedic surgeon in Los Angeles who designs hip implants said that he believed that the design of the ASR hip is prone to problems

43. Even the surgeon who designed the ASR hip, Dr. Thomas Schmalzried, admitted that DePuy had known since at least 2008 that the ASR cup may have problems. *The New York Times* reported in March 2010 that "Dr. Schmalzried said in an interview last month that he and DePuy officials realized within the last two years that the ASR cup might be more of a challenge to implant properly than competing cups." According to Dr. Schmalzried, "The window for component position that is consistent for good, long-term clinical function is smaller for the ASR," than other cups.

44. Despite its knowledge that the ASR hip had a defect and that it had failed hundreds of times, causing hundreds of patients to undergo the agony of another surgery, DePuy continued selling the defective hip implant. In so doing, DePuy actively concealed the known defect from

doctors and patients—including Ms. Layton and her doctor—and misrepresented that the ASR Hip System was a safe and effective medical device.

45. DePuy's reason to conceal the defect in its ASR Hip System is clear. In 2009 alone, DePuy brought in more than $5.4 billion in sales. Hip implant sales are critically important to DePuy's parent company, Johnson & Johnson, and DePuy is one of Johnson & Johnson's most profitable business groups. In 2006, DePuy was faced with a critical defect in one of its hip implant systems. The last thing DePuy wanted to do was to admit that these popular products had a critical defect that could cause a premature failure, forcing patients to have to undergo another painful surgery. Focused on corporate profits, and at the expense of patient safety, DePuy decided that it would not issue an embarrassing recall when it learned of the defects with its ASR Hip System in 2006. Moreover, motivated by greed rather than patient safety, DePuy did not even stop selling ASR Hip System. Instead, it continued to manufacture the hip implants and it continued to sell them to unsuspecting patients like Ms. Patricia Layton.

46. By early 2010, DePuy could no longer keep its secret. By then, the ASR hip had failed in 600 people, most of whom were forced to undergo a painful surgery to remove the defective ASR hip and replace it. But even after hundreds of people had been severely injured by its product, DePuy still didn't do the right thing by recalling its ASR hips.

47. In March 2010, DePuy finally began to disclose some of the alarming information about the ASR hip. It sent a letter to doctors warning them of the increased failure rate associated with the ASR Hip System. DePuy admitted that the ASR Hip System suffered from a "higher than expected revision rate," and that data compiled by the Australian National Joint Replacement Registry showed that 5.4 percent of the ASR Hips implanted had been surgically replaced after only three years and that the expected failure rate could be as high as 10 percent. The letter also

stated that DePuy was planning to stop selling the ASR hip, allegedly because of "declining demand."

48. On July 17, 2010, the FDA announced a nationwide recall related to the DePuy ASR Hip System. The FDA classified this recall as a Class 2 Recall. A Class 2 Recall includes situations where exposure to a violative product could cause a situation in which use of or exposure to a violative product may cause medically reversible adverse health consequences.

49. Most recently, on August 25, 2010, DePuy confirmed that in the first five years after implant alone, 13 percent of its ASR hip implants have failed and had to be surgically removed. DePuy also confirmed that at least 90,000 people have had ASR hips implanted in their bodies, meaning that over time, at least ***11,700 people*** will have an ASR hip failure and be forced to undergo a painful surgery to remove and replace it.

C. Plaintiff's ASR Hip was defective and failed, forcing her to undergo an additional painful and risky surgery

50. In 2008, PATRICIA LAYTON underwent a surgical procedure to implant the ASR HIP in her right hip. By this time, Defendants had already received several reports that the ASR Hip had failed, but DePuy refused to disclose that information to PATRICIA LAYTON, her physician, or the public. It would be another two years before DePuy would finally come clean and recall the ASR Hip due to its high failure rate.

51. After her right hip surgery, PATRICIA LAYTON began suffering from persistent debilitating pain in her right hip. It became increasingly painful for her to walk, to move her leg, and to rise from the seated position. PATRICIA LAYTON's pain increased to such an unbearable level that, at times, she was not able to walk, and she required pain medications.

52. Eventually her hip pain became unbearable, lab work was performed, and Plaintiff found out that she had increasingly elevated levels of cobalt and chromium in her blood, thus

revision was recommended. On February 10 2020, PATRICIA LAYTON underwent a complex, risky, and painful surgery (known as a "revision surgery") to remove the failed DePuy hip implant and replace it with a new hip implant. Revision surgeries are generally more complex than the original hip replacement surgery, often because there is a reduced amount of bone in which to place the new hip implants. Revision surgeries also usually take longer than the original hip replacement surgery and the revision surgery has a higher rate of complications.

D. The Defective ASR Hip and the Defendants' Conduct Caused Permanent Injuries and Substantial Damages to PATRICIA LAYTON

60. PATRICIA LAYTON recovery from the replacement surgery has been long and painful. To this day- more than a year after the revision surgery- she continues to suffer from pain and discomfort.

61. Having to go through a revision surgery subjected PATRICIA LAYTON to much greater risks of future complications than he had before the revision surgery. For example, several studies have found that revision surgery has a much higher risk of dislocation compared with an original hip replacement surgery. In one study conducted by Charlotte Phillips and her colleagues at Brigham and Women's Hospital in Boston, 14.4 percent of patients who underwent a revision surgery suffered from a dislocation compared with 3.9 percent of patients who underwent an original hip replacement surgery. In other words, hip replacement patients who have undergone a revision surgery are almost ***four times more likely*** to suffer from a hip dislocation than those who have not. (Phillips CB, *et al.* Incidence rates of dislocation, pulmonary embolism, and deep infection during the first six months after elective total hip replacement. *American Journal of Bone and Joint Surgery* 2003; 85:20–26.)

62. As a direct and proximate result of the failure of the defective hip system and the

Defendants' wrongful conduct described in this Complaint, PATRICIA LAYTON sustained and continues to suffer economic damages (including medical and hospital expenses), severe and possibly permanent injuries, pain, suffering and emotional distress. As a result thereof, Plaintiff has sustained and will continue to sustain damages in an amount to be proven at trial, but which will far exceed the $75,000 jurisdictional minimum of this court.

63. As a direct and proximate result of the failure of the defective DePuy ASR Hip System and Defendants' wrongful conduct, Plaintiff continues to sustain economic damages, grief, sorrow, mental anguish, emotional distress, and pain and suffering.

FIRST CAUSE OF ACTION
(Strict Product Liability)
Against all Defendants

64. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as to the Defendants, and each of them as follows:

65. Defendants designed, manufactured, promoted, distributed, marketed, and sold the DePuy ASR Hip System, including the ASR acetabular component.

66. At all times material hereto, the DePuy ASR Hip System that was designed, manufactured, promoted, distributed, marketed, and sold by the Defendants was expected to reach, and did reach, prescribing physicians and consumers, including Plaintiff without substantial change in the condition in which it was sold.

67. At all times material hereto, the DePuy ASR Hip System that was designed, manufactured, promoted, distributed, marketed, and sold by the Defendants was in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce. Such condition included, but is not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, the DePuy ASR Hip System contained manufacturing defects, subjecting Plaintiff and others to risks, including the risk that the acetabular component would not properly grow into the bone, causing the hip system to prematurely fail and requiring complex, risky, ad painful surgery to remove and replace the defective product;

b. When placed in the stream of commerce, the DePuy ASR Hip System contained unreasonably dangerous design defects and was not reasonably safe for the intended use, subjecting Plaintiff and others to risks, including the risk that the acetabular component would not properly grow into the bone, causing the hip system to prematurely fail and requiring complex, risky, ad painful surgery to remove and replace the defective product;

c. The DePuy ASR Hip System was insufficiently tested: and

d. The DePuy ASR Hip System was not accompanied by adequate instructions and/or warnings to fully inform Plaintiff and her physicians of the full nature or extent of risks associated with its use.

68. Defendants knew or should have known of the dangers associated with the use of the DePuy ASR Hip System, as well as the defective nature of the DePuy ASR Hip System. Despite this knowledge, Defendants continued to manufacture, sell, distribute, promote and supply the DePuy ASR Hip System so as to maximize sales and profits at the expense of the public health hand safety. Defendants' conduct was done in conscious disregard of the foreseeable harm cause by the DePuy ASR Hip System and in conscious disregard for the rights and safety of consumers such as Plaintiff.

69. PATRICIA LAYTON and her doctors used the DePuy ASR Hip System as directed for its intended purpose.

70. At all timed herein mentioned, the DePuy ASR Hip System was defective, and Defendants knew that it was to be used by the used without inspection for defect therein. Moreover, neither PATRICIA LAYTON nor her physician knew of had reason to know at the time of the use of the subject product, of the existence of the aforementioned defects. Neither PATRICIA LAYTON nor her physicians could have discovered the defects in the DePuy ASR Hip System through the reasonable exercise of care.

71. The DePuy ASR Hip System had not been materially altered or modified prior to its implantation in PATRICIA LAYTON.

72. As a direct and proximate result of the failure of the defective DePuy ASR Hip System, Plaintiff suffered the injuries and damages described herein.

SECOND CAUSE OF ACTION
(Negligence)
Against all Defendants

73. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as to the Defendants, and each of them as follows:

74. At all times herein mentioned Defendants had a duty to exercise reasonable care in the design, manufacture, testing, inspection, labeling, and sale of the DePuy ASR Hip System to ensure that it would be safely used in a manner and for a purpose for which it was made.

75. Defendants maliciously, recklessly and/or negligently failed to exercise ordinary care in the design, manufacture, testing, advertising, marketing, and sale of the DePuy ASR Hip System.

76. Defendants maliciously, recklessly and/or negligently failed in their duty to exercise reasonable care in the provision of an adequate warning to PATRICIA LAYTON and her physicians as to the risks of the DePuy ASR Hip System.

77. Defendants maliciously, recklessly and/or negligently failed to exercise reasonable care in the post-marketing warnings as to the risks of the DePuy ASR Hip System when they knew or should have known of said risks.

78. As a result of Defendants' wrongful conduct, Plaintiff suffered injuries and damages as alleged herein.

THIRD CAUSE OF ACTION
(Breach of Implied Warranties)
Against DePuy and DOES 1-10

79. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as to the Defendants, and each of them as follows:

80. Prior to the time that the DePuy ASR System was used by PATRICIA LAYTON, Defendants impliedly warranted to Plaintiff and her physicians that the DePuy ASR Hip System was of merchantable quality and fit for the use for which it was intended.

81. Plaintiff and Plaintiff's physicians were and are unskilled in the research, design, manufacture of the DePuy ASR Hip System, and they reasonably relied entirely on the skill, judgment and implied warranty of Defendants in using the DePuy ASR Hip System.

82. The DePuy ASR Hip System was neither safe for its intended use nor of merchantable quality, as warranted by Defendants, in that it had dangerous propensities when put to its intended use and would cause severe injuries to the user.

83. Defendants, by selling, delivering and/or distributing the defective DePuy ASR System to Plaintiffs, breached the implied warranty of merchantability and fitness and caused Plaintiff to suffer severe pain and emotional distress, incur medical expenses and incur a los of earning capacity.

84. As a result of the aforementioned breach of implied warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

FOURTH CAUSE OF ACTION
(Breach of Express Warranty)
Against DePuy and DOES 1-10

85. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as to the Defendants, and each of them as follows:

86. At all times herein mentioned, Defendants expressly warranted to Plaintiff and Plaintiff's physicians, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publication, package inserts and other written materials intended for physicians, medical patients and the general public, that he aforementioned DePuy ASR Hip System was safe, effective, fit an proper fort its intended use.

87. In utilizing the aforementioned DePuy ASR Hip System, Plaintiff and her physician relied on the skill, judgment, representations and foregoing express warranties of Defendants.

88. Said warranties and representations were false in that the aforementioned DePuy ASR Hip System was not safe and was unfit for the uses for which it was intended.

89. As a result of the foregoing breach of express warranties by Defendants, Plaintiffs suffered injuries and damages as alleged herein.

PRAYER FOR RELIEF

THEREFORE, Plaintiff Patricia Layton demands judgment for the following:

1. Past and future medical expenses and incidental expenses, according to proof;
2. Past and future loss of earnings and/or earning capacity, according to proof;
3. Past and future general damages, according to proof;
4. Punitive and exemplary damages in an amount to be determined at trial;

5. Prejudgment and post judgment interest;

6. Costs to bring this action; and

7. Such other and further relief as this Court may deem just and proper.

Dated: September 14, 2021

Respectfully Submitted,

NAPOLI SHKOLNIK, PLLC

By: _____

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SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK

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PATRICIA LAYTON,

Plaintiff,

-against-

DEPUY SYNTHES SALES, INC. d/b/a
DEPUY SYNTHES JOINT RECONSTRUCTION;
MEDICAL DEVICE BUSINESS SERVICES, INC.;
DEPUY ORTHOPAEDICS, INC.;
DEPUY SYNTHES PRODUCTS, INC.;
DEPUY SYNTHES, INC.; DEPUY MITEK, LLC;
DEPUY, INC.; DEPUY INTERNATIONAL, LTD.;
DEPUY IRELAND UNLIMITED COMPANY;
DEPUY SYNTHES JOHNSON & JOHNSON IRELAND,
LTD.; JOHNSON & JOHNSON INTERNATIONAL;
JOHNSON & JOHNSON; and JOHNSON & JOHNSON
SERVICES, INC.,

Defendants.

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SUMMONS and VERIFIED COMPLAINT

NAPOLI SHKOLNIK, PLLC
Attorneys for Plaintiff
400 Broadhollow Road, Suite 305
Melville, New York 11747
(212) 397-1000

By my signature below, the undersigned attorney certifies pursuant to 22 NYCRR §130-1.1-a that I have read the within papers and that, to the best of my knowledge and belief, the same are not frivolous as that term is defined in 22 NYCRR §130-1.1(c).

Nicholas R. Farnolo, Esq.

PLEASE TAKE NOTICE:

☐ NOTICE OF ENTRY

that the within is a (certified) true copy of an duly entered in the office of the clerk of the within named court on _____ 20____.

Dated:

Yours, etc.
NAPOLI SHKOLNIK, PLLC

Exhibit - 2

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK
INDEX NO. TC210914-S3

PATRICIA LAYTON, Plaintiff, v. DEPUY SYNTHES SALES, INC. d/b/a DEPUY SYNTHES JOINT RECONSTRUCTION; MEDICAL DEVICE BUSINESS SERVICES, INC.; DEPUY ORTHOPAEDICS, INC. ; DEPUY SYNTHES PRODUCTS, INC.; DEPUY SYNTHES, INC.; DEPUY MITEK, LLC; DEPUY, INC.; DEPUY INTERNATIONAL, LTD.; DEPUY IRELAND UNLIMITED COMPANY; DEPUY SYNTHES JOHNSON & JOHNSON IRELAND, LTD.; JOHNSON & JOHNSON INTERNATIONAL; JOHNSON & JOHNSON; and JOHNSON & JOHNSON SERVICES, INC., Defendants.	

NOTICE TO CLERK OF REMOVAL OF CIVIL ACTION

Defendants DePuy Orthopaedics, Inc., DePuy Synthes, Inc., DePuy Synthes Sales, Inc. DePuy Mitek LLC, Medical Device Business Services, Inc. f/k/a DePuy, Inc., Johnson & Johnson, Johnson & Johnson International, and Johnson & Johnson Services, Inc., by and through its undersigned counsel, and pursuant to 28 U.S.C. § 1446(d), hereby provide notice of removal of the above-captioned action to the United States District Court for the Eastern District of New York. This Notice of Removal has been filed in the United States District Court and a copy is attached hereto as **Exhibit A**.

Pursuant to 28 U.S.C. § 1446(d), filing this Notice with the Clerk of the State Court removes this action from the State Court to the United States District Court, "and the State Court shall proceed no further unless and until the case is remanded." 28 U.S.C. § 1446(d). Compliance with form and procedure of removal automatically removes the case from the State Court to the Federal District Court and, in general, any action taken by a State Court while notice of removal is pending in the Federal Court is void. *See Tarbell v. Jacobs,* 856 F.Supp. 101, 104 (N.D.N.Y. 1994); *see also Riveredge Owners' Ass'n v. Town of Cortlandt, Inc.,* 2016 WL 6462387, at *2 (S.D.N.Y. Nov. 1, 2016).

Please take further notice that the Clerk of this Court is requested to promptly deliver to the Clerk of the Court of the United States District Court for the Eastern District of New York all papers not in the original Court file.

Dated: October 13, 2021

Respectfully Submitted,

s/Michael C. Zogby

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Attorneys for Defendants DePuy Orthopaedics, Inc., DePuy Synthes, Inc., DePuy Synthes Sales, Inc.,DePuy Mitek LLC, Medical Device Business Services, Inc. f/k/a DePuy, Inc., Johnson & Johnson, Johnson & Johnson International, and Johnson & Johnson Services, Inc.